RE: UNITED STATES OF AMERICAN, ex rel. RYAN v. SIUH, LEDERMAN, ET AL.
Case No.: 04-CV-2483

Copy of Plaintiffs' Summons and Complaint

EXHIBIT 1

SLR:RKH:LDM
F# 2004V01161

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA *ex rel.* ELIZABETH M. RYAN,

Plaintiff,

- against -

STATEN ISLAND UNIVERSITY HOSPITAL, GILBERT LEDERMAN, GILBERT LEDERMAN, M.D., P.C. and PHILIP JAY SILVERMAN,

Defendants.

Civil Action
No. CV 04-2483

(Gleeson, J.)
(Pollak, M.J.)

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COMPLAINT OF THE UNITED STATES

Plaintiff, United States of America, for its Complaint against defendants Gilbert Lederman and Gilbert Lederman, M.D., P.C. (herein referred to together as the "Lederman defendants"), alleges as follows:

INTRODUCTION

1. This is a civil action for damages and penalties arising from the false and/or fraudulent claims submitted or caused to be submitted by the Lederman defendants for Medicare reimbursement to the Centers for Medicare & Medicaid Services ("CMS," and f/k/a the Health Care Financing Administration ("HCFA")), which is part of the United States Department of Health and Human Services ("HHS"), for purposes of obtaining payment or approval for payment, in violation of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, as amended, and at common law.

2. The FCA provides that any person who, with actual knowledge, or in reckless disregard or deliberate ignorance of the truth, submits or causes to be submitted a false or fraudulent claim to the United States Government for payment or approval is liable for a civil penalty of up to $11,000 for each claim, plus three times the amount of the damages sustained because of the false claim. The FCA further provides that under certain circumstances a person with information that false or fraudulent claims have been presented to the Government for payment may bring a lawsuit for the person and for the United States. These actions are called qui tam actions, and the person bringing the action is known as a relator and, subject to the provisions of the FCA, the relator may be entitled to share in any recovery made by the United States in the suit. The FCA requires that the complaint in a qui tam action be filed under seal without service on any defendant. The complaint remains under seal while the United States conducts an investigation of the allegations in the complaint and determines whether to join the action.

3. This action was originally filed under seal by relator Elizabeth M. Ryan (the "Relator") on or about June 16, 2004, pursuant to the qui tam provisions of the FCA, 31 U.S.C. § 3730(b).

4. On or about February 19, 2008, the United States filed a Notice of Partial Intervention against defendants Staten Island University Hospital ("SIUH"), Gilbert Lederman, and Gilbert Lederman, M.D., P.C. By an order of this Court dated February 25, 2008, the complaint filed by the Relator was unsealed.

5. The United States alleges that, from in or around 1996 through and including in and around December 2003, the Lederman defendants violated the FCA by knowingly submitting

claims to the United States under Part B of the Medicare Program for their professional services in connection with providing stereotactic body radiosurgery ("BRS"), a method of treating cancer by delivering radiation below the neck at much higher doses than conventional radiation therapy, which method, at all relevant times, was not covered by the Medicare Program. Additionally, the Lederman defendants knowingly used incorrect Current Procedural Terminology ("CPT") billing codes for the BRS professional services that they billed under Part B. As a result, the Lederman defendants received Medicare reimbursement to which they were not entitled.

JURISDICTION AND VENUE

6. This action arises under the FCA, as amended, 31 U.S.C. §§ 3729 - 3733. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. §§ 1331, 1345, 1367(a).

7. This Court has personal jurisdiction over the Lederman defendants because they submitted claims for payment to, and received payments from, the United States in this district, and because defendant Gilbert Lederman, upon information and belief, resides in this district.

8. Venue is proper in this Court under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a), in that the Lederman defendants conducted business in this district and the events or omissions which give rise to this action occurred in this district.

PARTIES

9. The United States of America is the plaintiff in this action. It sues on behalf of CMS, an agency and instrumentality of the United States which administers the Medicare Program.

10. Relator Elizabeth M. Ryan is a resident of Florida.

11. Defendant Gilbert Lederman was at all times relevant hereto, but is not currently, the director of the Radiation Oncology department at SIUH, a hospital located in Staten Island, New York. Upon information and belief, Gilbert Lederman is a resident of Staten Island, New York.

12. Defendant Gilbert Lederman, M.D., P.C. was at all times relevant hereto a professional corporation owned exclusively by defendant Gilbert Lederman, and through which Gilbert Lederman billed Medicare for professional services that he and other radiation oncologists provided at SIUH. Based upon records filed with the New York State Department of State, Gilbert Lederman, M.D., P.C. is incorporated under the laws of the State of New York and maintains its principal place of business at 227 East 19th Street in New York, New York. As used herein, "the Lederman defendants" or "defendants" shall refer to both Gilbert Lederman and Gilbert Lederman, M.D., P.C.

BACKGROUND TO THE MEDICARE PROGRAM.

13. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the costs of certain health care services. Entitlement to Medicare is primarily based on age and disability. See 42 U.S.C. §§ 426, 426A.

14. The Secretary of HHS administers Medicare through CMS.

15. The Medicare Program comprises two parts, Part A and Part B. Medicare Part B provides federal government funds to help pay for, among other things, certain physician or professional services provided to Medicare beneficiaries. 42 C.F.R. §§ 410.1 and 410.3.

16. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the United States Treasury. Eligible individuals who are age

65 or older, or disabled, may enroll in Part B to obtain benefits in return for payments of monthly premiums as established by HHS. 42 U.S.C. §§ 1395j, 1395o, 1395r. The items and services covered by Part B include certain physician services. 42 U.S.C. §§ 1395k, 1395l, and 1395x(s).

17. The United States provides reimbursement for Medicare claims through CMS. CMS, in turn, contracts with private insurance carriers who, acting on behalf of CMS, administer, process and pay Part B claims. 42 C.F.R. § 421.5(b). Part B claims for the professional services of physicians are administered by the carriers from the Federal Supplementary Medical Insurance Trust Fund (the "Part B Trust Fund"). 42 U.S.C. § 1395u. At all times relevant hereto, the Lederman defendants submitted Medicare claims to Empire Medicare Services ("Empire"), which has since changed its name to National Government Services, Inc. Empire acted on behalf of CMS as the carrier for Part B claims.

18. Physician services are billed to Medicare carriers using standard 5-digit billing codes. These billing codes are based on the "Physicians' Current Procedural Terminology" or CPT codes, which were established by the American Medical Association ("AMA"). A listing of descriptive terms and identifying CPT codes for reporting medical services is contained in the CPT manual, which is published and updated annually by the AMA.

19. The use of CPT codes has simplified the reporting of services and is intended to ensure that the procedure or service rendered by the physician was accurately identified. The AMA in its introduction to the CPT manual specifically states that "[i]nclusion of a descriptor and its associated specific five-digit identifying code number in this category of CPT codes is generally based upon the procedure being consistent with contemporary medical practice and being performed by many physicians in clinical practice in multiple locations." In its foreword to

the CPT manual, the AMA declares that the CPT coding system "is the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs."

20. Providers, such as the Lederman defendants, must comply with applicable statutes, regulations and guidelines in order to be reimbursed by Medicare Part B. In that regard, providers are obligated to familiarize themselves with the statutes, regulations and guidelines regarding coverage by Medicare of items and services.

21. Private insurance carriers with whom CMS contracts locally to administer, process, and pay Part B claims issue guidance as to whether a particular item or service is covered in the form of Local Coverage Determinations ("LCDs"). 42 C.F.R. § 400.202.

22. Physicians submit claims for Medicare reimbursement on the CMS (formerly HCFA) 1500 Form. By submitting a CMS/HCFA 1500 Form to Medicare, a physician certifies that the services billed were performed and were medically necessary. When submitting a claim for reimbursement, a physician agrees that she/he will submit claims that are "accurate, complete and truthful."

23. On a CMS/HCFA 1500 Form, the physician must state, among other things, the CPT code applicable to the service provided.

24. Each CMS/HCFA 1500 Form contains the following notices to physicians:

> **NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.**
>
> **NOTICE: Anyone who misrepresents or falsifies essential information to receive payment from Federal funds requested by**

this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

25. In addition, each CMS/HCFA 1500 Form contains the following certification provision whereby the Lederman defendants certified that the BRS professional services that they provided were covered and thus reimbursable by Medicare:

SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE . . .): I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare . . . regulations.

26. Upon receiving a claim, the Medicare carrier determines the reimbursement amount for the claim as 80% of the lesser of the actual charge or fee schedule under the appropriate CPT code, subject to other applicable deductibles. The Medicare beneficiary, or his or her supplemental insurance carrier, is required to pay the remaining 20 percent. This 20 percent is sometimes referred to as a "co-payment."

MEDICARE GUIDANCE THAT BRS WAS A NON-COVERED PROCEDURE

27. During the relevant period, two LCDs addressed the extent to which stereotactic radiosurgery was covered under the Medicare Program. Both LCDs, which were issued by Empire in its role as carrier, stated that BRS was not covered, i.e. not reimbursable, under Part B.

28. Specifically, on October 21, 1996, Empire issued a LCD regarding coverage for stereotactic radiosurgery, which it described as the "deliver[y of] high doses of ionizing radiation to a small intracranial target, usually 4 cm or less in diameter." The October 21, 1996 LCD

further refers to treatment for diagnoses of the brain and nervous system and limits coverage for stereotactic radiosurgery to diagnosis codes for such conditions.

29. Thereafter, Empire issued a second LCD, effective August 2001 through November 2004, that expressly excludes from coverage stereotactic radiosurgery treatment for indications below the neck. It states "[t]he treatment of below the neck diseases such as lung carcinoma with stereotactic radiosurgery is considered investigational at this time." The August 2001 LCD also refers to many of the same diagnosis codes that relate to conditions of the brain and nervous system.

30. Both LCDs advise physicians to use CPT code 61793 when billing for stereotactic radiosurgery. CPT code 61793 was listed by the AMA as a type of surgery to treat conditions of the "Nervous System," and is listed under the anatomical subheading "Skull, Meninges, and Brain." The main term for this code was "stereotaxis" which refers to neurosurgery and neurological research for locating points within the brain. During the relevant time period, there was no CPT code for BRS.

31. According to the August 2001 LCD, code 61793 could be billed only once per course of treatment regardless of the number of sessions required. Similarly, in the CPT code book, the AMA states that the code covers one or more fractions.

FACTUAL BACKGROUND

32. During the relevant period of in or around 1996 through and including in and around December 2003, Gilbert Lederman was the director of the Radiation Oncology department at SIUH. The Lederman defendants provided BRS and other forms of cancer treatments to patients at SIUH on both an in-patient and out-patient basis. Through Gilbert

Lederman, M.D., P.C., Gilbert Lederman employed physicians to provide BRS as well as other cancer treatments at SIUH.

33. The Lederman defendants submitted, or caused to be submitted, to Medicare more than 300 claims for reimbursement for BRS professional services on CMS/HCFA 1500 Forms, even though such services were not covered by Medicare. Each of the more than 300 claims represented BRS professional services provided by the Lederman defendants to a Medicare beneficiary.

34. Upon information and belief, the Lederman defendants are in actual or constructive possession of all relevant information and records concerning the more than 300 claims which they submitted to Medicare for payment.

35. The Lederman defendants received a copy of the two LCDs by mail.

36. The Lederman defendants knew that Medicare did not cover BRS.

37. The claims that the Lederman defendants submitted, or caused to be submitted, were miscoded, as the BRS services were improperly billed as services under CPT code 61793.

38. The Lederman defendants also improperly billed BRS services under code 77432, which applied to the radiation treatment management of cerebral lesions.

39. In addition, multiple sessions were separately billed under codes 61793 and 77432, even though the AMA prescribed that these codes be used only once per course of treatment and the August 2001 LCD prescribed that code 61793 be billed only once per course of treatment of the brain and nervous system.

40. As a result of the Lederman defendants' submission of the false or fraudulent claims on CMS/HCFA 1500 Forms, Medicare reimbursed the Lederman defendants for BRS

services that were not covered by Medicare.

FIRST CLAIM FOR RELIEF
False Claims Act, 31 U.S.C. §3729(a)(1) - False Claims

41. The United States realleges and incorporates by reference paragraphs 1 through 40 as though fully set forth herein.

42. By virtue of the conduct described above, including the misuse of CPT codes, the Lederman defendants presented or caused to be presented claims for payment to the United States knowing such claims were false, fictitious, or fraudulent or acting with reckless disregard or deliberate ignorance of the truth or falsity of such claims in violation of 31 U.S.C. §3729(a)(1).

43. The United States paid the false claims because of the acts of the Lederman defendants.

44. By reason of these payments, plaintiff the United States has been damaged in an amount to be determined at trial, plus a $10,000 civil penalty for each such false claim presented or caused to be presented before October 1999 and a $11,000 civil penalty for each such false claim presented or caused to be presented after September 1999.

45. Under the FCA, plaintiff the United States is entitled to treble damages, plus a civil penalty for each violation.

SECOND CLAIM FOR RELIEF
False Claims Act, 31 U.S.C. §3792(a)(2) - False Statements

46. The United States realleges and incorporates by reference paragraphs 1 through 40 as though fully set forth herein.

47. By virtue of the conduct described above, including the submission to Medicare of

reimbursement claims on CMS/HCFA 1500 Forms containing, among other misstatements, an improper CPT code, the Lederman defendants knowingly made or used, or knowingly caused to be made or used, false records or statements to get false and fraudulent claims paid or approved by officials of the United States Government, in violation of 31 U.S.C. §3729(a)(2).

48. Because of the conduct set forth in this claim for relief, the United States has been damaged in an amount to be determined at trial, plus a $10,000 civil penalty for each such false claim presented or caused to be presented before October 1999 and a $11,000 civil penalty for each such false claim presented or caused to be presented after September 1999.

49. Under the FCA, plaintiff the United States is entitled to treble damages, plus a civil penalty for each violation.

THIRD CLAIM FOR RELIEF
Unjust Enrichment

50. The United States realleges and incorporates by reference paragraphs 1 through 40 as though fully set forth herein.

51. By virtue of the foregoing, the Lederman defendants were unjustly enriched by receiving payments from the United States for Medicare reimbursement claims on CMS/HCFA 1500 Forms for a service that was not covered, to the detriment of the United States, in an amount to be determined at trial.

FOURTH CLAIM FOR RELIEF
Payment Under Mistake of Fact

52. The United States realleges and incorporates by reference paragraphs 1 through 40 as though fully set forth herein.

53. By virtue of the foregoing, the United States paid the Lederman defendants for

Medicare reimbursement claims under a mistake of fact, to wit, that the Lederman defendants' claims for Medicare reimbursement were submitted for a non-covered procedure on CMS/HCFA 1500 Forms containing the wrong CPT code, and the United States has been damaged in an amount to be determined at trial.

WHEREFORE, plaintiff the United States demands and prays that judgment be entered in its favor against the Lederman defendants as follows:

54. On Claims I and II, awarding plaintiff treble the amount of damages it sustained, in an amount to be established, and all allowable penalties, fees and costs under the FCA;

55. On Claim III, awarding plaintiff damages in the amount the Lederman defendants were unjustly enriched, pre-judgment interest, plus fees and costs;

56. On Claim IV, awarding plaintiff the amount it mistakenly paid the Lederman defendants, pre-judgment interest, plus fees and costs;

57. The cost of this action, including investigation costs, plus interest, as provided by law; and all other necessary and proper relief.

Dated: July 31, 2008
Brooklyn, NY

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